UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO: ALL ACTIONS	CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris

[REDACTED VERSION] DECLARATION OF DONALD E. HAVILAND, ESQUIRE, IN SUPPORT OF PLAINTIFFS' RESPONSE TO TRACK 2 DEFENDANTS' MEMORANDUM REGARDING HAROLD BEAN

I, Donald E. Haviland, Jr., Esquire, hereby declare that:

1. I am co-managing attorney of the New Jersey office of Kline & Specter and an attorney in the Philadelphia office of Kline & Specter, P.C. I am one of the attorneys for plaintiffs in this litigation and I worked directly with my client, the proposed consumer class representative Harold L. Bean, in complying with this Court's directives in it's April 3, 2006 Case Management Order No. 24 regarding discovery and briefing on the issue of Class Certification with respect to Track 2 Defendants in the above captioned action. As such, I have personal knowledge of the below facts and would testify to them if called upon to do so in support of the Plaintiffs' Response to Track 2 Defendants' Memorandum Regarding Harold Bean.

2. Except as set forth herein by the supplemental submissions attached hereto, the record necessary for this Court to determine Mr. Bean's adequacy and typicality to serve as a representative plaintiff as to Track 2 Class 1 is included in my two prior submissions to the Court, to wit, (1) Declaration of Donald E. Haviland, Jr. Esquire in Support of Plaintiffs'

Proposed Consolidated Class Certification Order with Respect to Track 2 Defendants (specifically at ¶¶ 35-37 and Exhibits "M" and "N" thereto), filed May 8, 2006, and (2) Declaration of Donald E. Haviland, Jr., Esquire in Support of Plaintiffs' Reply Memorandum in Support of Proposed Consolidated Class Certification Order with Respect to Track 2 Defendants (specifically at ¶¶ 63-83 and Exhibit "N") filed July 18, 2006.

3. Attached hereto as Ex. A is a true and correct copy of the Transcript of the Oral Deposition of Harold R. Bean taken on August 18, 2006 in this case.

4. Defendants go to great lengths to try to undermine Mr. Bean's purchases of Epogen – as evidenced by clear billing and payment records. They do this by arguing that, since Amgen licensed epoetin alfa (Epogen) to J&J/Ortho for exclusive sale in the cancer marketplace, Mr. Bean could not have received Epogen for his cancer-driver anemia. Defendants' efforts to undermine the records fails because both Amgen and J&J/Ortho cheated on the licensing agreement, engaging in widespread "spillover" or "out-of-market" sales, as the below evidence proves.

Evidence supporting Mr. Bean's purchases of Amgen's Epoetin Alfa ("Epogen")

5. In September 1985, Amgen Inc. ("Amgen") entered into a licensing agreement with Johnson & Johnson's affiliate Ortho Pharmaceutical Corporation [now called Ortho Biotech Products, L.P.] ("Ortho") relating to "certain patented technology and know-how of [Amgen] to sell a genetically engineered form of recombinant human erythropoietin, called Epoetin alfa, throughout the United States for all human uses except dialysis and diagnostics." Ex. B (Amgen 2000 Annual Report at 36) (http://www.amgen.com/pdfs/Investors_2000_AnnualReport.pdf).

6. The License Agreement required Amgen and Ortho "to compensate each other for Epoetin alfa sales that either party makes into the other party's exclusive market, sometimes

described as "spillover" sales." *Id.* Amgen "established and [employed] an audit methodology to measure each party's spillover sales and to allocate the net profits from those sales to the appropriate party." *Id.*

7. As far back as November 11, 1996, a protein chemist at Amgen posted the following commentary respecting the "spillover sales" phenomena in his response to a thread on the BioNet's Proteins USENET newsgroup: "In fact, fairly often hospital pharmacies only carry one of these two products, so PROCRIT can end up being used in dialysis patients or EPOGEN in AIDS patients. The two companies have a [*sic*] agreement on how to compensate each other for such "out of market" sales." Attached hereto as Ex. C is a true and correct copy of John Philo, "EPOGEN and PROCRIT" (http://www.bio.net/bionet/mm/proteins/1996-November/004769.html).

8. Over the years, "[a] number of disputes have arisen between Amgen and Johnson & Johnson as to their respective rights and obligations under the various agreements between them, including (the "License Agreement")." Ex. B (Annual Report at 36).

9. In the latest round of such dispute, in October 2005, Ortho brought an action against Amgen in the United States District Court for the District of New Jersey, alleging violations of the Sherman Antitrust Act, namely "an anti-competitive tying arrangement and pricing scheme implemented by defendant Amgen in the oncology clinic market." *See generally* Complaint, *Ortho Biotech Products, L.P. v. Amgen Inc.*, Case No. 2:05-cv-04850-SRC, at ¶ 1 *et seq.* (attached hereto as Ex. D).

10. At his August 5, 2005 deposition in this litigation, John Dempsey – a former National Account Manager for Ortho – testified that his "[redacted]" from 1990 to 1993, the years immediately after its launch. *See* excerpts from the Deposition of

John Dempsey at 18:13-14 (attached as Ex. E). In that capacity, his task involved "[redacted]" *Id.*, at 18:22, 19:1. Typically, Mr. Dempsey would explain to potential customers "[redacted]" *Id.*, at 20:14-16.

11. According to Mr. Dempsey's testimony, however, Ortho "[redacted]", clarifying that "[redacted]" *Id.*, at 25:15-17. As the retail, non-dialysis market had been allocated exclusively to Ortho under the License Agreement, Ortho deemed it "[redacted]" *Id.*, at 25:18-19.

12. He testified that Amgen and Ortho "[redacted]" *Id.*, at 112:12-17.

13. Because Ortho was "[redacted]" Ortho had to begin offering discounts on Procrit®. *Id.*, at 27:20-22, 28:1-3.

14. Ortho also sought to differentiate itself from Amgen through "[redacted]" which "[redacted]" *Id.*, at 22: 18-19. Similarly, where "[redacted]" *Id.*, at 22:20-22.

15. With respect to the existence of "[redacted]" Mr. Dempsey confirmed directly that, [redacted] *Id.*, at 111:20-22, 112:1.

16. Ortho's contracts with individual physicians or physician practices involve mostly oncologists and nephrologists. *Id.*, at 115:13-15. With regard to the oncology sector, Mr. Dempsey confirmed [redacted] *Id.*, at 116:6-7.

17. At his August 25, 2005 deposition, Jeffrey A. Stewart, Vice President of Compliance at Ortho Biotech further explained the concept of "[redacted]" *See* excerpts from the Deposition of Jeffrey A. Stewart at 10:21-22, 11:1-3 ("[redacted]") (attached as Ex. F).

18. At her August 12, 2005 deposition, former J&J employee Carol Webb defined her understanding of the spillover agreement: ("[redacted]" *See* excerpts from the Deposition of Carol Webb at 146:9-13 (attached as Ex. G).

19. Similarly, Ms. Webb testified that [redacted] *Id.*, at 150:19-22 and 156:14-17. *See also* Ex. F (Stewart Dep. at 79:21-22).

20. In his April 28, 2006 Declaration in this litigation, another former Ortho employee Mark Duxbury described epoetin alfa as "the ultimate commodity because Epogen and

Procrit were the identical substance and provided the same clinical benefits, and were reimbursed at the same or virtually the same amount in the dialysis and non-dialysis sectors." *See* Declaration of Mark Duxbury ("Duxbury Decl."), ¶ 10 (attached hereto as Ex. H). In other words, notwithstanding whatever indication appears on their respective labels, either drug can be used interchangeably, and will yield the same results when administered to a patient. Ad importantly for this litigation, the inflated AWP reimbursement rates were "the same or virtually the same."

21. In order to "persuade customers to switch from Epogen to Procrit," Ortho tasked Mr. Duxbury and its other sales representatives with "promot[ing] the clinical benefits and greater profit and margin available to the customer from Procrit based on the difference between acquisition cost and reimbursement." *Id.*

22. Mr. Duxbury testified that "Procrit purchasers in dialysis and/or non-dialysis areas knew that Medicare reimbursed for Epoetin alfa," and were well aware of the financial considerations involved. *See generally,* Ex. H (Duxbury Decl, ¶¶ 15-17).

23. On several occasions, Ortho's management "directed" Mr. Duxbury to "promote Procrit to freestanding dialysis centers" – despite the parameters of the License Agreement with Amgen. *See id.*, ¶¶ 22-24.

24. Although during his deposition, Mr. Dempsey expressed doubts that Amgen would currently be promoting Epogen® in the oncology sector, because now "[redacted]" *see* Ex. E (Dempsey Dep. at 136:2-4), [redacted]

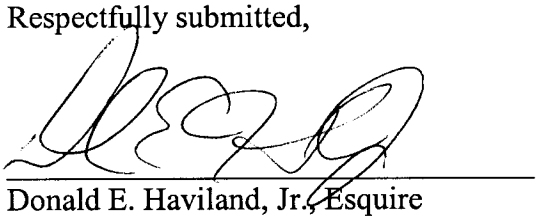
25. For instance, the Federal Register dated August 5, 2004 (Vol. 69, No. 150) contains the text of a proposed rule regarding "Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005: Proposed Rule", at pp. 47487-47430 (http://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/04-17312.htm). That proposed rule states, in relevant part: "Oncologists administer a number of drugs that are changing in payments by different amounts. For instance, oncologists' highest Medicare revenue drug Q0136 (EPOGEN; PROCRIT), would decline in payment by 7 percent . . ." *Id.*, at 47563. [Attached hereto, in excerpted form, as Ex. I.] The clear indication by the proposed Rule is an awareness that, not only are oncologists administering Epogen for non-ESRD purposes, but that oncologists were billing it under the Q0136 J-code reserved for Procrit.

26. More recently, the State of New York's Office of Medical Management, Department of Health published its Medicaid Update for November 2005, Vol. 20, No. 12 (http:// www.health.state.ny.us/health_care/medicaid/program/update/2005/nov2005.htm), which contains a section entitled "Billing for Epogen, Aranesp, Neupogen, and Neulasta." [Attached hereto as Ex. J.] Significantly, this document refers expressly to "Epoetin Alfa (**Epogen**) (for non-ESRD use) per 1,000 Units" as being reimbursable for "**Practitioners**" (including physicians) under the procedure code Q0136. *Id.* (boldface in original). It proceeds to further distinguish **"Chemotherapy Clinics"**, which can bill Q0136 for "Epoetin alfa (**Procrit**) (for non-ESRD use) per 1,000 Units." *Id.*

27. I declare under penalty of perjury under the laws of the Commonwealth of Pennsylvania that the foregoing is true and correct and that this Declaration was prepared in the Commonwealth of Pennsylvania on September 5, 2006.

Date: September 5, 2006

Respectfully submitted,



Donald E. Haviland, Jr., Esquire
KLINE & SPECTER
A PROFESSIONAL CORPORATION
1525 Locust Street, 19th Floor
Philadelphia, PA 19102
215-772-1000 telephone
215-735-0957 facsimile

CO-LEAD COUNSEL FOR PLAINTIFFS AND THE CLASS

CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE

Docket No. MDL 1456

I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on September 5, 2006, I caused copies of **[REDACTED VERSION] DECLARATION OF DONALD E. HAVILAND, ESQUIRE, IN SUPPORT OF PLAINTIFFS' RESPONSE TO TRACK 2 DEFENDANTS' MEMORANDUM REGARDING HAROLD BEAN** to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Steve W. Berman

Steve W. Berman